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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,919	01/16/2004	Revital Lifshitz-Liron	1662/62403	1513

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,919	LIFSHITZ-LIRON ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-17* is/are allowed.

6)☒ Claim(s) *18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-24 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed June 11, 2004 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449, (1 sheet), the cited references have been considered. The references cited on the attached form PTO-892 and not relied on herein are included to show the general state of the art.

Allowable Subject Matter

Claims 1-17 are directed to a process for making risedronate sodium which is substantially free of iron which comprises refluxing risedronic acid, a sodium base and an iron-reducing amount of EDTA in a liquid and isolating risedronate sodium, which is substantially free of iron, from the combination. None of the references of record teach such a process and therefor claims 1-17 are in condition for allowance.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51

U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable. See also MPEP §§ 2112, 2112.02 and 2145(II).

Multiple Reference 35 U.S.C. § 102 Rejections

A rejection under 35 U.S.C. § 102 based on multiple references is made herein. The additional reference is relied on to explain the meaning of a term used in the primary reference or else to show that a characteristic not disclosed in the primary reference is inherent. Accordingly, the Examiner's reliance on multiple references is proper. "Normally, only one reference should be used in making a rejection under 35 U.S.C. § 102. However, a 35 U.S.C. § 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent." (See MPEP § 2131.01).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(I) Claims 18-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Aronhime et al., (U.S. Patent Application Publication No. 2003/0195170, cited by Applicants).

Aronhime et al. teach risedronate sodium crystalline form B, (page 2, paragraph [0018] "form B"), a pharmaceutical composition comprising pure form B and at least one pharmaceutically acceptable excipient, (page 4, paragraph [0056] and page 10, paragraph [0163] – page 11, paragraph [0178], and a method of treating osteoporosis, a disease characterized by a progressive loss of bone, (page 1, paragraph [0003]), which includes a step of administering said composition, (page 19, claim 139).

Present claims 21-24 require a risedronate sodium substantially free of iron. This requirement is met because, as noted above, pure form B is taught. Also, nowhere does the reference disclose the addition of or the presence of iron.

In the present claims, the risedronate sodium or form B is defined in terms of the process of making it where risedronate sodium is produced free of iron. Thus, the claims are evaluated the same as "product by process" type claims, (see MPEP § 2113) where it is not necessary that a reference teach the actual process steps in order to be relevant. Because the product of the reference is taught to be pure, it would appear to be substantially identical to the present risedronate sodium indicated to be free of iron. Thus, the Examiner has met his burden required for rejecting the claims. In particular, as set forth under MPEP § 2113, "[o]nce the examiner

provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)".

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

(IIa) Claims 18-24 are rejected under 35 U.S.C. 102(a) **or** 102(a) as being anticipated by Cazer et al. (U.S. Patent No. 6,410,520, cited by the Examiner "Cazer '520").

(IIb) In the alternative, Claims 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cazer et al. (WO 01/56983, published August 9, 2001, cited by the Examiner, "Cazer '983").

Both Cazer et al. references contain the same disclosure and thus the following applies equally to each of the above rejections.

Cazer et al. teach risedronate sodium in a crystalline form, (see Example 2 at col. 4 of Cazer '520 and the corresponding page, lines of Cazer '983). Aronhime et al. (U.S. Patent Application Publication 2003/0195170), is here relied on to show what this disclosure of Cazer '520 means or else to show that which is inherent in the teachings of Cazer '520, (see the above cited section of MPEP §2131.01). In particular, Aronhime et al. teaches at page 2, paragraph

[0016] that the disclosure at Example 2 of Cazer '520 indicates, *inter alia* risedronate sodium in crystalline form B, (hereinafter "form B").

Cazer '520 further disclose a pharmaceutical composition comprising form B and at least one pharmaceutically acceptable excipient, (col. 5, line 54 – col. 6, line 65; and the corresponding section of Cazer '983), and a method of treating osteoporosis or else a patient for bone loss, (col. 1, lines 22-35, and the corresponding section of Cazer '983).

Present claims 21-24 require a risedronate sodium substantially free of iron. This requirement is met because no where in the reference is it taught to add iron to the composition or else the presence of iron in the process of producing the active ingredient.

In the present claims, the risedronate sodium or form B is defined in terms of the process of making it where risedronate sodium is produced free of iron. Thus, the claims are evaluated the same as "product by process" type claims, (see MPEP § 2113) where it is not necessary that a reference teach the actual process steps in order to be relevant. Because the product of the reference is not taught to be in association with iron, it would appear to be substantially identical to the present risedronate sodium indicated to be free of iron. Thus, the Examiner has met his burden required for rejecting the claims. In particular, as set forth under MPEP § 2113, "[o]nce the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)".

Double Patenting (Provisional)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, 124-129, 138 and 140-147 of copending Application No. 10/337,676, (Atty. Docket 1662/60105) where pure crystalline form B risedronate sodium, compositions thereof and methods of treating osteoporosis are taught.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference, if any, between the present and the co-pending claims is that the co-pending claims fail to contain an express limitation indicating that iron is not present. However, given that iron is not taught to be included in the process of preparing the risedronate sodium compound, it is not seen the risedronate of the present claims and that of the co-pending claims are patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

For the above reasons, claims 18-24 are deemed properly rejected and are not presently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

June 3, 2007